K030544
(1)

510(k) SUMMARY

AUG 14 2008

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201 Fax: 215-256-9191
Contact:	Jean Callow
Date Prepared:	February 26, 2008

B. Trade Name:

Trade Name:	Unassigned
Device Name:	CT Injectable Safety Huber Needle
Common Name:	Intravascular Administration Set,
Classification:	FPA
C.F.R. Section:	880.5440
Class:	II

C. Predicate Device: K071846, EZ Huber Safety Infusion Set, PFM Medical, Inc.

D. Device Description:

The CT Injectable Safety Huber Needle is composed of a sharpened anti-coring Huber style needle for port septum access having a safety feature which is manually operated and will prevent accidental needle sticks when advanced which is connected to a conventional style extension set for attachment to standard IV/Drug infusion line sets.

The proximal end of the needle cannula is adhesively sealed to the molded housing which contains a glue well and fluid thru hole. The fluid thru hole leads to the distal end of the extension line set that is also adhesively bonded in the molded housing. The distal end of the extension tubing contains a female luer connector with removable dust cap on the proximal end creating a fluid path from the needle tip thru the female luer. The infusion set is also offered in a configuration where the extension tubing contains a Y-Site connector with removable dust cap placed midway between the needle and the female luer connector. The extension tubing contains purple pigment to indicate its use for high pressure. The Y portion of the connector is a molded female luer that is sealed with a removable dust cap. A non-removable pinch clamp is located between the female luer and needle cannula. On line sets with a Y-Site connector, two pinch clamps are present located between the female luer and the Y-Site and the Y-Site and the needle cannula. The pinch clamps are designed that when engaged, fluid flow is restricted thru the extension tubing.

The needle cannula is constructed with a Huber style anti-coring needle tip. The cannula is stainless steel and is shielded by a removable star needle guard of plastic construction.

The molded wing housing is of plastic construction and contains rigid protruding wings. The under side of the wings contain a foam comfort pad. The comfort pad is constructed with an adhesive backing which is secured to the wing housing.

The molded wing housing is snap fitted into the molded housing via a securement post. The wing housing is of plastic construction with a protruding wing designed flush with the under surface of the housing. The wing housing contains a thru hole that easily slides over the needle cannula. The wing housing contains a torsion spring that is positioned on a post and is orientated in a positioning channel. The torsion spring is in a compressed state until the molded housing is removed from the wing housing at which time the torsion spring is automatically activated. The wing housing consists of a base to which the securement bag is adhesively bonded.

The molded housing is connected to the wing housing via the securement bag. The securement bag (a polyester film lamination) is adhesively bonded to the molded housing and the wing housing. The securement bag is compressed (accordion style) between the molded housing and wing housing and is of length sufficient to activate the torsion spring and to prevent the needle tip from entering the securement bag area.

In normal operation, the molded housing is activated during removal of the needle from the patient. The wing housing is held firmly in place while the molded housing is disengaged. The molded housing is disengaged from the wing housing by grasping the elevated portion of the molded housing and sliding the molded housing in an upward direction. The molded housing will disengage from the wing housing and will advance until the torsion spring is past the needle tip at which time the torsion spring will snap over the needle access hole. Upon spring activation, there will be an audible click sound as the spring snaps against the wing housing. The securement bag prevents the molded housing from advancing off the needle cannula and the torsion spring prevents the needle from advancing out of the housing.

Prior to use, the exposed portion of the needle cannula, including the sharpened needle tip area, is coated with a silicone fluid to render the needle lubricious and to reduce the insertion (penetration) and drag force to industry acceptable values.

Each needle size has I.D. Rings located within the pinch clamp to identify the appropriate infusion rate for the noted needle gauge size. Components will be assembled by the manufacturer into standard configurations with or without the "Y-Site" and packaged.

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E. Intended Use:

The CT Injectable Safety Huber Needle is a device used to administer fluids from a container to a patient's vascular system through an implanted port. The CT Injectable Safety Huber Needle incorporates an active safety feature that aids in the prevention of accidental needle sticks.

The CT Injectable Safety Huber Needle is a safety needle designed with an anti-coring needle tip configuration. The primary use for Huber Needles is to deliver solutions to implanted ports. The safety feature is designed to protect the practitioner from accidental needle sticks.

The CT Injectable Safety Huber Needle is compatible with power injection procedures up to 300 psi.

F. Performance Data:

Pressure testing has been performed on each needle gauge size to determine pressure ratings. Pressure ratings for the appropriate needle gauge is located on the I.D. Ring located within the infusion line clamp.

Clinical studies were not deemed necessary since no changes have been made to the design, packaging, sterilization or indications for use that would have any effect on the safety and effectiveness of the device when compared to the legally marketed predicate device.

G. Comparison to Predicate Devices:

The CT Injectable Safety Huber Needle is identical in design, safety aspects, packaging, sterilization and indications for use as the predicate PFM Medical, EZ Huber Safety Infusion Set. All materials have been used in previous cleared submissions.

There are no new differences in the intended use of the proposed and predicate devices which would raise any issues in the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2008

Ms. Jean Callow
Regulatory Specialist
Medcomp
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K080544
Trade/Device Name: CT Injectable Safety Huber Needle
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: August 6, 2008
Received: August 8, 2008

Dear Ms. Callow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

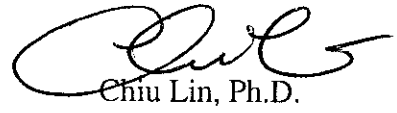
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080544

Device Name: CT Injectable Safety Huber Needle

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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